DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 14, 2015

G21 S.r.l.
Mr. Maurizio Foroni
President
Via Sandro Pertini, 8
41039 San Possidonio (MO)
ITALY

Re: K150408
Trade/Device Name: V-STEADY and V-FAST
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, NDN
Dated: October 30, 2015
Received: November 2, 2015

Dear Mr. Foroni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150408

Device Name
V-STEADY and V-FAST

Indications for Use *(Describe)*
V-STEADY and V-FAST bone cements are indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) Summary has being submitted in accordance with the requirements of 21 CFR 807.92 and the FDA's guidance The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)].

1. General Information

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Summary Preparation Date:	December 4, 2015

2. Device

Device Name:	V-STEADY and V-FAST
Classification name:	Polymethylmethacrylate (PMMA) bone cement
Product Code:	LOD NDN
Regulation number:	888.3027
Class:	II

3. Predicate Device

The subject devices family (V-STEADY and V-FAST) is substantially equivalent to the following legally marketed predicate device:

Applicant	Device name	510(k) Number	Product code
HERAEUS KULZER GMBH	OSTEOPAL®V	K050085	LOD NDN

Additionally, reference devices, as listed below, were selected only to provide scientific or technical information to support the subject devices.

Applicant	Device name	510(k) Number	Product code
TECRES SPA	MENDEC SPINE	K042415	LOD NDN
STRYKER CORPORATION	STRYKER VERTAPLEX HV	K091606	LOD NDN

4. Device Description

V-STEADY and V-FAST are polymethylmethacrylate (PMMA) based bone cements formulated to perform percutaneous vertebral augmentation procedures, such as vertebroplasty or kyphoplasty. Bone cements are self-curing systems consisting of liquid and powder components:

- the powder component is constituted of PMMA beads shaped particles containing the initiator benzoyl peroxide required for starting initiating the cement curing. The radiopacifier agent, zirconium dioxide, is necessary for the cement visibility under radiographs but it does not take part of the curing process (radical polymerization).
- The liquid component comprises the monomer, methylmemethylmethacrylate (MMA); dimethyl-para-toluidine (DMPT) as polymerization accelerator and hydroquinone (HQ) as stabilizer to prevent polymerization of the liquid during storage.

The specific content of PMMA and benzoyl peroxide is slightly different between the two cements conferring upon them specific properties. V-STEADY bone cement has an immediate development of viscosity and thus it is a high viscosity cement that maintains its properties throughout the useful working time. The V-FAST has a low initial viscosity and a long working time allowing to work extremely carefully especially when a good time margin before polymerization is required.
Both the liquid and powder components are supplied sterile. The sterile-filtered monomer component is supplied in an amber glass ampoule (10 ml) and comes in a blister pack sterilized by ethylene oxide. The polymer powder component is supplied in a double sterile packaging.

The sterilization process is ethylene oxide and it has been properly validated.

Preparation and application procedures of the subject devices are detailed within the labeling as Mixing Phase, Waiting Phase, Application Phase, Setting/Hardening Phase.

5. Indications for use

V-STEADY and V-FAST bone cements are indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a vertebroplasty or balloon kyphoplasty procedure.

6. Comparison of technological characteristics with the predicate devices.

V-STEADY and V-FAST bone cements share many of the same technological characteristics compared to the predicate device, OSTEOPAL V, including fundamental features such as chemical formulation, packaging configuration, sterilization methods, mechanical performances and handling phases. There are however few differences in shelf life, presence of coloured pigment in the predicate only, as detailed in the table below:

	G21 device family		**Predicate Device**
	V-STEADY	**V-FAST**	**OSTEOPAL V (K050085)**
Chemical composition			
Powder Component	Polymethylmethacrylate (PMMA) Zirconium Dioxide (ZrO_2) Benzoyl Peroxide (BPO)	Polymethylmethacrylate (PMMA) Zirconium Dioxide (ZrO_2) Benzoyl Peroxide (BPO)	Polymethylmethacrylate (PMMA) Zirconium Dioxide (ZrO_2) Benzoyl Peroxide (BPO)
Liquid Component	Metylmethacrylate (MMA) N,N-dymethyl-p-toluidine (DMPT) Hydroquinone (HQ)	Metylmethacrylate (MMA) N,N-dymethyl-p-toluidine (DMPT) Hydroquinone (HQ)	Metylmethacrylate (MMA) N,N-dymethyl-p-toluidine (DMPT) Hydroquinone (HQ)
Other constituents	None	None	Chlorophyll
Shelf Life	1 year	1 year	5 years

7. Performance Data

The following performance data are provided in support of the substantial equivalence determination:

- **Biocompatibility**

As recommended by the FDA's Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo), the subject devices comply with ISO 10993.

- **Sterilization**

The sterilization process (including both the ethylene oxide method (powder component and aseptically processed, filled glass vials) as well as the filter-sterilization (liquid component)) has been validated and the sterility of the subject devices has been verified according to ISO 11135:2014, ISO 11138-1:2006, ISO 10993-7:2009, ISO 14161:2009, ISO 14937:2009, ISO 11737-1:2006, ISO 11737-2:2009, ISO 13408-1:2008 and ISO 13408-2:2003.

- **Material, Mechanical and Performance Characterization**

A comprehensive set of performance testing was conducted to characterize V-STEADY and V-FAST bone cements as compared to the predicate, according to the FDA's Guide "Class II Special Controls Guidance Document: polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA".

Results show comparable performances to the predicate and reference devices, and are in compliance with ASTM F451-08, ISO 5833:2002, ASTM F2118-14, ASTM D2990-09, ASTM D638, and ASTM E399-12.

8. Conclusions

The subject device family has the same classification and intended use as the predicate device. Also, several tests were conducted as recommended by the FDA's Guide "Class II Special Controls Guidance Document: polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" to address safety and performance characteristics (e.g. biocompatibility, sterilization, shelf life, chemical and mechanical tests). The obtained results demonstrate that the subject devices perform as intended in the specific use conditions and comply with applicable standards, similarly to the predicate device. Thus, on the basis of evidence discussed above, the V-STEADY and V-FAST can be deemed substantially equivalent to the predicate device K050085.